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Section 5 – 510(k) Summary

510(k) Summary
Pelvic Muscle Therapy
Colonial Medical Supply,
1350 E Flamingo Ave #343
Las Vegas, Nv 89119
Prepared: August 30th 2000

1. Contact Person

Patricia Leigh
Phone:- 800 634 9334
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2. Name of the Medical Device

Proprietary name:- Pelvic Muscle Therapy
Classification name:- Perineometer
Common/usual name: Pelvic Muscle Exerciser

3. Device Classification

The Pelvic Muscle Therapy System is classified by he FDA under the heading of Perineometer (21CRF Section 884.1425) as a Class 11 device with Product Code 85HIR.

4. Statement of Substantial Equivalence.

The Pelvic Muscle Therapy System is substantially equivalent to the DesChutes Medical Products Reflex Treatment System (510(k) K994079.

A comparison of the Pelvic Muscle Therapy and the Reflex Treatment System is Presented in Tables 5.1 and 5.2.

5. Description of Device.

The Pelvic Muscle Therapy System is a comprehensive, behaviorally based program Designed for independent use by incontinent people at home. The kit includes a Personal training device, an instruction video, instructional manual and direct clinical Support via phone and Internet. The main device is the pneumatically based trainer, Which is hand held and connected to the vaginal sensor. The strength of the muscle Contraction is reflected on dial on the monitor.

6. Intended Use/Indications

The Pelvic Muscle System is intended for the identification and strengthening Of the pelvic floor muscles, which has been found to help women with incontinence.

7. Substantial Equivalence Comparison.

Tables 5.1 and 5.2 demonstrate the relative regulatory classifications and Technological characteristics of the two devices.

Table 5.1 Comparison of Regulatory Classifications

Category	Colonial Medical Supply Pelvic Muscle Therapy	DesChutes Medical Reflex Treatment System
Common or usual Name	Pelvic muscle exerciser	Pelvic muscle exerciser
Classification Name	884.1425 Perineometer	884.1425 Perineometer
Product Code	85 HIR	85HIR
Intended Use/ Indications	Treatment of stress and/or Urge incontinence in females	Treatment of stress and/or Urge incontinence in female
Prescription device	NO	NO

Table 5.2 Comparison of Device Technological Characteristics

Feature	Colonial Medical Supply Pelvic Muscle Therapy	DesChutes Medical OTC Reflex
Target Population	Women with Mild incontinence	Women with mild Incontinence.
Single Patient Device	Yes	Yes
Single Use or reusable	Reusable	Reusable
Requires regular visits To medical personnel	No	No
Sterilization Status	Clean, but not sterile	Clean, but not sterile
Biofeedback display Information	Numerical response to muscle contraction strength	LED display muscle contraction strength

Material Sensor	Medical grade silicone (polydimethylsiloxane)	Medical grade silicone (polydmethylsiloxane)
Biocompatibility	Balloon sensor testing exceeds Guidelines set forth in ISO 10993 Testing results indicate material is Biocompatible, nontoxic and well Tolerated by mucosal membranes	Balloon sensor testing exceeds guidelines set forth in ISO 10993 testing results indicate material is biocom-patible, nontoxic and well Tolerated by mucosal Membranes.
Chemical Safety	Addressed by biocompatibility Testing (ISO 10993)	Addressed by biocompat-ibility testing (ISO 10993)
Number of models	One (female)	One (female)
Anatomical Sites	Vagina	Vagina
Instructions	Patient instruction for home use Video and manual	Patient instruction for home use Journal
Energy Use and/or Delivered	None pneumatic device	Energy supplied 3AAA Replaceable batteries.
Packaging	Sensors in sealed plastic bag Monitor,Video,manual in Card Board box	Sensors inside plastic bag trainer and journal inside cardboard box.

8. Summary of Safety and Efficacy Testing

A. Extensive biocompatibility and safety testing of silicone material used in the balloon sensors was performed for Colonial Medical Supply by Toshiba Silicone Co.,Ltd

B. Clinical Performance Data

The Pelvic Muscle Therapy System has been extensively tested for its safety and efficacy in alleviating symptoms of stress and /or urge incontinence. In addition, clinical testing of the product demonstrated that the device can be used outside the supervision of a licensed practitioner, and adequate directions for use have been prepared.

The conclusive data from this clinical study demonstrated that otherwise healthy women of a wide age range with symptoms of urge and /or stress incontinence can improve their symptoms by strengthening their pelvic floor muscles, and identifying the correct muscle group is key to this end. All study participants who completed the study saw some degree of symptom improvement. 46% reported a complete obliteration of their symptoms, 32% reported improvement. With an overall success rate of 78%.

9. Conclusion

The Pelvic Muscle Therapy System has been shown to be safe and efficacious for its intended use through extensive biocompatibility testing of the material that comes into contact with the mucosal membranes, the study conducted to demonstrate the efficacy of the self directed instructions and resulting data demonstrating that all study participants who completed the 16 week program realized some degree of improvement of their incontinent symptoms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Ms. Patricia Leigh, R.N.
General Manager
Colonial Medical Supply
1350 East Flamingo Road #343
LAS VEGAS NEVADA 89119

Re: K002830
Pelvic Muscle Therapy
Dated: November 15, 2000
Received: December 01, 2000
Regulatory Class: II
21 CFR §884.1425/Procode: 85 HIR

Dear Ms. Leigh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K002830

Applicant :- Colonial Medical Supply

Device Name :- Pelvic Muscle Trainer

Indications for Use of the Pelvic Muscle Trainer

Pelvic Muscle Trainer assists the user to perform Kegel exercises, which may help in the treatment of urinary incontinence.

David C. Ayerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002830

Over-the-Counter Use ✓